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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,214	09/21/2005	Ivan Salgo	US030075	9554

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EXAMINER	
DIVERSE, PIERRE P	
ART UNIT	**PAPER NUMBER**
2624	

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08/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,214	SALGO ET AL.	
	Examiner	Art Unit	
	PIERRE DIVERSE	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 – 19 are pending in this application.

2. Acknowledgement is made of applicant's preliminary amendment filed on 09/21/2005.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 09/21//2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 14 are directed to “a method for guiding the placement or observing the operation”. Observation and guidance are two different actions, it is not clear as to which action the claims are directed to.

8. Claim 15 is directed to “an ultrasonic surgical guidance imaging system which acts to guide the placement or observe the operation”. Observation and guidance are two different actions, it is not clear as to which action the claims are directed to.

Claim Objections

9. Claim 9 is objected to because of the following informalities: Claim 9 has the number 130 in parenthesis "(130)". Examiner has assumed that this was left in error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1 – 5, 10 – 12 and 14 – 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Strommer et al., U.S. Patent Application Publication 2002/0049375 filed on Sep. 7, 2001 ("Strommer").

12. Regarding claim 1, Strommer discloses 'a method of guiding the placement or observing the operation of an invasive medical device' (see [0030]). Strommer specifically suggests a method and system for medical imaging and navigation in medical in-vivo invasive probing.

'operating an invasive medical device from an invasive medical device system to perform an activity within a body' (see Fig 15A; Fig. 16 A; [0030]). Strommer specifically suggests the operation for in-vivo invasive probing which constitutes operating an invasive medical device within a body.

'operating an ultrasonic diagnostic imaging system to guide or observe the invasive medical device by means of a real time three dimensional ultrasonic image' (see [0101]; [0190]; [0191]). Strommer specifically suggests that the two dimensional image acquisition can be an ultrasound and that the system produces a "3D road map" for the surgeon;

'producing information with the invasive medical device system having coordinate information relating to the activity' (see [0114]; [0119]; [0191]). Strommer specifically suggests that the MPS system processes the detected electromagnetic fields and provides the three dimensional location and orientation of the MPS sensors and that the surgical tool (invasive medical device) has an MPS sensor; and

'merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information' (see [0096]; [0034]; [0269]; [0266]). Strommer specifically suggests that after insertion of the surgical tool the system detects the location and orientation of the MPS detector mounted on the tool and superimposes it on the three-dimensional image.

13. Regarding claim 2, Strommer discloses 'wherein the invasive medical device includes a position sensor' (see [0031]) . Strommer specifically suggests a surgical tool MPS sensor attached to the surgical tool; and

'wherein producing information with the invasive medical device system comprises producing coordinate information in response to signals received from the position sensor' (see [0114]; [0119];[0191]). Strommer specifically suggests that the MPS system processes the detected electro-magnetic fields and provides the three dimensional location and orientation of the MPS sensors; the surgical tool has an MPS sensor.

14. Regarding claim 3, Strommer discloses 'wherein the position sensor comprises a receiver which receives signals in the acoustic, optical radio frequency, or electromagnetic spectrum' (see [0114]). Strommer specifically suggests that the MPS system processes the detected electro-magnetic fields and provides the three

dimensional location and orientation of the MPS sensors; this teaches that the reception signals in the electromagnetic spectrum.

15. Regarding claim 4, Strommer discloses 'wherein the position sensor comprises a transmitter (see [0103]; Strommer specifically suggests an MPS transmitter) which transmits signals in the acoustic, optical, radio frequency, or electromagnetic spectrum' (see [0114]). Strommer specifically suggests that the MPS system processes the detected electro-magnetic fields and provides the three dimensional location and orientation of the MPS sensors.

16. Regarding claim 5, Strommer discloses 'wherein merging information further comprises merging locational information into the real time three dimensional ultrasonic image at locations where activity of the invasive medical device has been performed' (see [0096]; [0119]; [0120];[0122]). Strommer specifically suggests that after insertion of the surgical tool the system detects the location and orientation of the MPS detector mounted on the tool and superimposes it on the three-dimensional image.

17. Regarding claim 10, Strommer discloses 'further comprising acquiring ECG data' (see Figure 1, item 106; [0100]; [0102]). Strommer specifically suggests that the ECG monitor continuously detects an electric timing signal of the heart during inspection or surgery; and

'further comprising displaying both the real time three dimensional ultrasonic image containing merged information from the invasive medical device system and an ECG trace' (see [0121]; [0135]; figure 18 and figure 20). Figure 18 and figure 20 depict the three dimensional image and the ECG trace being displayed.

18. Regarding claim 11, Strommer discloses 'wherein merging information further comprises merging locational information into the three dimensional ultrasonic image at locations where activity of the invasive medical device has been performed' (see [0096]; [0119]; [0120]; [0122]). Strommer specifically suggests that after insertion of the surgical tool the system detects the location and orientation of the MPS detector mounted on the tool and superimposes it on the three-dimensional image.; and

'wherein displaying further comprises displaying a plurality of ECG traces related to the locations where the activity of the invasive medical device has been performed'. (see [0250]; [0251]; figure 18 and figure 20). Strommer specifically suggests that different ECG traces can be displayed by pressing the forward and backward buttons and that they are displayed with three dimensional image of the inspected organ. Figure 18 and figure 20 depict the three dimensional image and the ECG trace.

19. Regarding claim 12, Strommer discloses 'wherein operating an ultrasonic diagnostic imaging system further comprises producing a volume rendered three dimensional anatomical ultrasonic image in real time' (see [0095]). Strommer specifically suggests constructing a three dimensional image from the recorded two

dimensional images and displaying the three dimensional images synchronized with real time;

20. Regarding claim 14, Strommer discloses 'a method of guiding the placement or observing the operation of an invasive medical device with a three dimensional ultrasonic imaging and invasive medical device operating system' (see [0030]). Strommer specifically suggests a method and system for medical imaging and navigation in medical in-vivo invasive probing

'operating an invasive medical device by means of an interventional device subsystem to perform an activity within a body' (see Fig 15A; Fig. 16 A; [0030]). Strommer specifically suggests the operation for in-vivo invasive probing which constitutes operating an invasive medical device within a body;

'acquiring ultrasonic echo information by means of an ultrasonic imaging subsystem from a volumetric region containing the invasive medical device' (see [0101]; [0119]). Strommer specifically suggests that the two dimensional image acquisition can be an ultrasound and that when the surgical tool is located within the inspected organ (volumetric region) a two dimensional image can contain a portion of the tool;

'producing information from the invasive medical device having coordinate information relating to the activity' (see [0114]; [0119]; [0191]). Strommer specifically suggests that the MPS system processes the detected electromagnetic fields and provides the three dimensional location and orientation of the MPS sensors and that the surgical tool (invasive medical device) has an MPS sensor;

'producing a real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information from the ultrasonic echo information and the information from the invasive medical device' (see [0096]). Strommer specifically suggests that after insertion of the surgical tool the system detects the location and orientation of the MPS detector mounted on the tool and superimposes it on the three-dimensional image; and

'displaying the real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information on an image display' (see figure 6; Figure 22; [0034]; [0269]; [0266]). Strommer specifically suggests displaying three dimensional images according to a real time reading with the location and orientation of a surgical tool superimposed.

21. Regarding claim 15, Strommer discloses 'An ultrasonic surgical guidance imaging system which acts to guide the placement or observe the operation of an invasive medical device' (see [0030]). Strommer specifically suggests a method and system for medical imaging and navigation in medical in-vivo invasive probing.

'an ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric region for image guidance of the placement or operation of an invasive medical device' (see [0031]; [0101]). Strommer specifically suggests a two-dimensional imaging transducer and that it can be ultrasound;

'an ultrasound acquisition subsystem coupled to the ultrasonic probe' (see [0031]; [0101]; [0102]). Strommer specifically suggests that the two-dimensional image

acquisition device (ultrasound acquisition system) includes an image transducer (probe) and that it can be ultrasound;

'an invasive medical device' (see [0031]). Strommer specifically suggests a surgical tool;

'an interventional device subsystem coupled to the invasive medical device' (see [0128]; [129]). Strommer specifically suggests an inner body radial image transducer mounted in a catheter along with the surgical tool;

'a 3D image processor coupled to the ultrasound acquisition subsystem and the interventional device subsystem' (see figure 1; abstract; [0031]). Strommer specifically suggests that the processor is coupled to the two-dimensional imaging system (ultrasound acquisition subsystem).

'which operates to produce 3D ultrasound images containing locational information of the invasive medical device in real time' (see [0038]). Strommer specifically suggests that the processor associates each of the two-dimensional images with the respected location and orientation information and reconstructs a three-dimensional image; and

'an image display coupled to the 3D image processor' (see figure 1). Strommer specifically suggests the display (item 130) coupled to the processor.

22. Regarding claim 16, Strommer discloses 'wherein the invasive medical device further includes a position sensor' (see [0031]). Strommer specifically suggests a surgical tool MPS sensor attached to the surgical tool; and

'wherein the interventional device subsystem further includes a device position measurement subsystem coupled to the position sensor' (see figure 1, items 162, 120 and 108; [0031]); Strommer specifically suggests an Medical Positioning System (item 108) coupled to the sensor (item 162) that is attached to the surgical tool (item 120)

23. Regarding claim 17, Strommer discloses 'wherein the 3D image processor is further responsive to locational signals produced by the device position measurement subsystem' (see [0038]; [0031]). Strommer specifically suggests that the processor associates each of the two-dimensional images with the respected location and orientation information and reconstructs a three-dimensional image and that the location and orientation are provided by the MPS (device position measurement subsystem).

24. Regarding claim 18, Strommer discloses 'further comprising acquiring parametric data' (see Figure 1, item 106; [0100]; [0102]). Strommer specifically suggests that the ECG monitor continuously detects an electric timing signal of the heart during inspection or surgery; the electric timing signal of the heart is parametric data; and

'further comprising displaying both the three dimensional ultrasonic image containing merged information from the invasive medical device system and a parametric image in real time' (see [0121]; [0135]; figure 18 and figure 20). Figure 18 and figure 20 depict the three dimensional image and the ECG trace image (parametric image).

25. Regarding claim 19, Strommer discloses 'wherein the parametric image is formed of at least one of ECG/electrical signals, tissue Doppler signals, strain rate signals, thickening measurements, or regional motion' (see [0121]; [0135]; figure 18 and figure 20). Figure 18 and figure 20 depict the three dimensional image and the ECG trace image (parametric image);

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

27. Claims 6 - 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strommer et al., U.S. Patent Application Publication 2002/0049375 filed on Sep. 7, 2001 ("Strommer") as applied to claim 1 above, and further in view of Hashimoto et al., U.S. Patent No. 6,245,017 published on Jun 12, 2001 ("Hashimoto").

28. Regarding claim 6, Strommer discloses 'processing ultrasonic echo information (see [0101]; Strommer specifically suggests capturing two dimensional image data of an area within the patient).

It is noted that Strommer does not specifically disclose that the processing is done 'to produce a real time three dimensional wire frame model of a volumetric region

of the body'. However, within the same field of endeavor, Hashimoto does disclose to produce a real time three dimensional wire frame model of a volumetric region of the body' (see column 7, lines 41 – 55; column 9, lines 45 - 50). Hashimoto specifically suggests generating a wire frame model from b-mode image data that represents a 3d scan region within a human body and that it is done real time.

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Hashimoto with those of Strommer in order to not only construct three dimensional images from two dimensional images (Strommer [0033]) but to also use wire frame models that allow for recognition by intuition of morphological information (Hashimoto column 8, lines 30 – 35).

29. Regarding claim 7, Strommer discloses 'merging locational information into the real time three dimensional model at locations where activity of the invasive medical device has been performed'. (see [0119]; [0120]; [0121]; [0122]). Strommer specifically suggests superimposing the location and orientation of the surgical tool to three dimensional image.

It is noted that Strommer does not specifically disclose that the three dimensional model as a "three dimensional wire frame model". However, within the same field of endeavor, Hashimoto does disclose a 'three dimensional wire frame model' (see column 7, lines 41 – 55). Hashimoto specifically suggests generating a wire frame model from b-mode image data that represents a 3d scan region within a human body.

30. Regarding claim 8, Strommer discloses 'ultrasonic echo information to produce a volume rendered ultrasonic image in real time' (see [0095]; [0101]). Strommer specifically suggests constructing a three-dimensional (volume rendered) image from the two dimensional images ([0101]; ultrasonic echo information) and displaying a sequence synchronized with real time; and

'displaying both the volume rendered ultrasonic image' (see [0269]. Strommer suggests displaying the three dimensional (volume rendered) image.

It is noted that Strommer does not specifically suggests displaying the 'three dimensional wire frame model'. However within the same field of endeavor Hashimoto does disclose displaying the 'three dimensional wire frame model' (see column 7, lines 46 – 55). Hashimoto specifically suggests the display of the wire-frame model.

31. Regarding claim 9, Strommer discloses 'merging locational information into at least one of the three dimensional wire frame model (130) and the volume rendered ultrasonic image at locations where activity of the invasive medical device has been performed'. (see [0096]; [0034]; [0269]; [0266]). Strommer specifically suggests that after insertion of the surgical tool the system detects the location and orientation of the MPS detector mounted on the tool and superimposes it on the three-dimensional image; in superimposing the tools location on the three-dimensional (volume rendered) image the location information is merged with the three dimensional (volume rendered) image.

32. Regarding claim 13, Hashimoto discloses 'producing a real time three dimensional wire frame model of an anatomical region of the body' (see column 7, lines 41 – 55). Hashimoto specifically suggests generating a wire frame model from b-mode image data that represents a 3d scan region within a human body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PIERRE DIVERSE whose telephone number is (571)270-3911. The examiner can normally be reached on Monday to Thursday 8:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pierre Diversé/
Examiner, Art Unit 2624

/P. D./

/Brian Q Le/
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